

REMARKS/ARGUMENTS

Status of the Claims

Upon entry of the present amendment, claims 1-34 and 36-39 are pending. Claims 1-8, 12-14, 17, 19 and 39 are withdrawn from consideration, pending the allowability of a generic or linking claim. Claim 9 is amended for consonance between the preamble and the body of the claim.

Rejection under 35 U.S.C. § 102(a) over WO 01/53312

The Examiner has rejected claims 9-11, 15-16, 18, 24-32, 34 and 36-37 under 35 U.S.C. § 102(a) as allegedly anticipated by WO 01/53312 ("Tang"). The Examiner concedes on page 5 of the present Official Action that Tang does not say anything about a compound that modulates cellular proliferation. Applicants do not agree that Tang anticipates the claimed methods. However, in the interest of furthering prosecution, Applicants have amended claim 9 to set forth the language of identifying of compound that modulates cellular proliferation in the body and the preamble of the claim.

Accordingly, the Examiner is respectfully requested to withdraw this rejection.

Rejection under 35 U.S.C. § 103(a) WO 01/53312 in view of U.S. Patent No. 5,650,501

The Examiner has rejected claims 9, 15-16, 18, 26-31 and 34 under 35 U.S.C. § 103(a) as allegedly obvious over Tang in view of U.S. Patent No. 5,650,501 ("the '501 patent"). This rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference must teach or suggest all the claims limitations. MPEP§2143. *See also, In re Rouffet*, 47 USPQ2d 1453. The court in *Rouffet* stated that "even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that

suggests the claimed combination.” *Rouffet* at 1459. The court has also stated that actual evidence of a suggestion, or teaching, or motivation to combine is required and the showing of a suggestion, or teaching, or motivation to combine must be “clear and particular.” *In re Dembiczak*, 50 USPQ2d 1614, 1617 (1999). Also, the Examiner must avoid using impermissible hindsight reconstruction by applying information gleaned only from Applicant’s disclosure. MPEP§2141(II)(C) and 2145(X)(A). Further, a conclusion of obviousness requires that the references relied upon be enabling in that they put the public in possession of the claimed invention. MPEP§21440.8(II)(B), *citing In re Hoeksema*, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968).

Here, there exists no motivation or suggestion to combine the disclosures of Tang and the ‘501 patent. Tang discloses a serine/threonine kinase sequence without teaching or suggesting any method of using the sequence for identifying a compound that modulates cellular proliferation, as conceded by the Examiner (page 5 of the present Official Action). The ‘501 patent discloses identifying potential stimulators or inhibitors of cell proliferation (column 5, lines 12-14 of the ‘501 patent), but discloses serine/threonine kinase sequences that are beyond the ambit of the sequences disclosed in Tang (and in the present application) of what the U.S. Patent Office would consider enabled under Section 112 (*i.e.*, beyond 95% sequence identity). In particular, the ‘501 patent discloses a serine/threonine kinase amino acid sequence (SEQ ID NO:4) with less than 80% sequence identity to the full-length of the amino acid sequence of SEQ ID NO:2 of the present application and the cited sequence in Tang (*see*, Exhibit A submitted with the Official Action mailed on March 25, 2005). Further, the ‘501 patent discloses a serine/threonine kinase nucleic acid sequence (SEQ ID NO:3) with about 80% sequence identity to the full-length nucleic acid sequence of SEQ ID NO:1 of the present application and the cited sequence in Tang (*see*, Exhibit A submitted with the Official Action mailed on March 25, 2005). There is a 20% differential in sequence identity between the serine/threonine kinase sequences disclosed in Tang and the ‘501 patent.

Further, the serine/threonine kinase sequences identified in Tang refer to GenBank accession number Y13115 (*see*, Table 2 of Tang). GenBank accession number

Y13115 references Karn, *et al.*, *Oncology Reports* (1997) 4:505-510 (Reference BC in the IDS submitted on June 19, 2002). Karn expressly identifies that human SAK is not expressed in proliferative active tissues examined (*see*, Karn at page 509), in direct contrast to *murine* SAK, which *murine* SAK is the subject of the '501 patent. Based on the disclosure of Karn, those of skill would have no motivation to practice the methods of the '501 patent using the sequence of Tang. The disclosure of Karn teaches against using the sequence of Tang in the methods of the '501 patent, and certainly teaches against a nexus of human SAK and cellular proliferation.

In view of the foregoing, those of skill in the art would have no motivation or suggestion to believe that the methods disclosed in the '501 patent could be carried out using the sequences disclosed in Tang. Absent impermissible hindsight reconstruction using information gleaned only from Applicant's specification, those of skill in the art would have no reason to combine the disclosures of Tang and the '501 patent.

Accordingly, the Examiner is respectfully requested to withdraw this rejection.

Rejection under 35 U.S.C. § 103(a) WO 01/53312 in view of U.S. Patent No. 5,650,501 and further in view of U.S. Patent No. 5,959,081

The Examiner has rejected claims 9, 15 and 20-23 under 35 U.S.C. § 103(a) as allegedly obvious over Tang in view of the '501 patent and U.S. Patent No. 5,959,081 ("the '081 patent"). This rejection is respectfully traversed for the reasons discussed above. There is no motivation or suggestion to combine the disclosure of Tang and the '501 patent. There is no motivation or suggestion to further include the disclosure of the '081 patent, because the '081 does not disclose or suggest anything about serine/threonine kinases in general or SAK kinases in particular. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

Rejection under 35 U.S.C. § 103(a) WO 01/53312 in view of U.S. Patent No. 5,650,501 and further in view of U.S. Patent No. 5,589,356

The Examiner has rejected claims 9, 15 and 20-23 under 35 U.S.C. § 103(a) as allegedly obvious over Tang in view of the '501 patent and U.S. Patent No. 5,589,356 ("the '356

Appl. No. 10/026,021
Amdt. dated January 26, 2006
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group 1642

PATENT

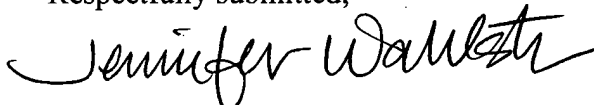
patent"). This rejection is respectfully traversed for the reasons discussed above. There is no motivation or suggestion to combine the disclosure of Tang and the '501 patent. There is no motivation or suggestion to further include the disclosure of the '356 patent, because the '356 does not disclose or suggest anything about serine/threonine kinases in general or SAK kinases in particular. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Jennifer L. Wahlsten
Reg. No. 46,226

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: 415-576-0300
Attachments
ASP:jlw
60666369 v1